



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Budahazi *et al.*

Appl. No.: 10/719,978

Filed: November 24, 2003

For: **Process for Purification of Plasmid
DNA**

Confirmation No.: 1745

Art Unit: 1645

Examiner: *To be assigned*

Atty. Docket: 1530.0550001/EKS/LAV

**First Supplemental Information Disclosure Statement
under 37 C.F.R. § 1.97(b)**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on April 23, 2004 in connection with the above-captioned application. Copies of documents **AN2-AM4** and **AS1-AR15** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached Form PTO-1449 are submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **AM3** and **AN3** cited on Form PTO 1449:

Document **AM3**, German Patent No. DE 43 21 904 is in the German language. An English language abstract of document **AM3** is attached as document **AT14**.

Document **AN3**, Japanese Patent No. JP 09-509313 is in the Japanese language. An English language abstract of document **AN3** is attached as document **AR15**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency,
or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

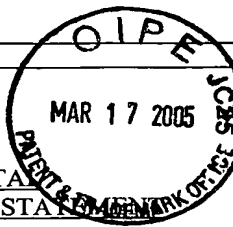
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FORM PTO-1449

ATTY. DOCKET NO.
1530.0550001/EKS/LAVAPPLICATION NO.
10/719,978APPLICANT(S)
Budahazi *et al.*FILING DATE
November 24, 2003ART UNIT
1645FIRST SUPPLEMENTARY
INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	4,900,677	02/13/1990	Hewitt			09/26/1986
	AB2	4,923,978	05/08/1990	McCormick			12/28/1987
	AC2	4,935,342	06/19/1990	Seligson <i>et al.</i>			12/01/1986
	AD2	4,946,952	08/07/1990	Kiefer			04/01/1988
	AE						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN2	EP 0 512 767 A1	11/11/1992	Europe			Yes No
	AO2	EP 0 512 768 A1	11/11/1992	Europe			Yes No
	AP2	EP 0 517 515 A2	12/09/1992	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	1	Birnboim, H.C., and Doly, T., "A rapid alkaline extraction procedure for screening recombinant plasmid DNA," <i>Nucleic Acids Res</i> 7:1513-1523, Oxford University Press (1979)
	AT	1	Bolivar, F., <i>et al.</i> , "Construction and Characterization of New Cloning Vehicles II. A Multipurpose Cloning System," <i>Gene</i> 2:95-113, Elsevier/North-Holland (1977)

EXAMINER

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 92/13963	08/20/1992	WIPO			Yes No
	AM3	DE 43 21 904 A1	01/12/1995	Germany			Yes X No
	AN3	JP 09-509313	09/22/1997	Japan			Yes X No
	AO3	WO 98/05767	02/12/1998	WIPO			Yes No
	AP3	EP 0 742 820	04/02/2003	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Bywater, M., <i>et al.</i> , "A Novel Chromatographic Procedure for Purification of Bacterial Plasmids," <i>Analytical Biochemistry</i> 132:219-224, Academic Press (1983)
	AS	<u>2</u>	Cole, K.D., "Purification of Plasmid and High Molecular Mass DNA Using PEG-Salt Two-Phase Extraction," <i>BioTechniques</i> 11:18-24, Eaton Publishing Company (1991)
	AT	<u>2</u>	Diogo, M.M., <i>et al.</i> , "Separation and Analysis of Plasmid Denatured Forms Using a Hydrophobic Interaction Chromatography," <i>Analytical Biochemistry</i> 275:122-124, Academic Press (1999)

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	AL4	WO 2004/060277	07/22/2004	WIPO			Yes No
	AM4	EP 0 920 497 B1	01/26/2005	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Ferreira, G.N., <i>et al.</i> , "Downstream processing of plasmid DNA for gene therapy and DNA vaccine applications," <i>TIBTECH</i> 18:380-388, Elsevier Science Ltd (2000)
	AS	<u>3</u>	Godson, G.N., <i>et al.</i> , "A Simple Method of Preparing Large Amounts of Φ X174 RF I Supercoiled DNA," <i>Biochimica et Biophysica Acta</i> 299:516-520, Elsevier (1973)
	AT	<u>3</u>	Goldberg, S., and Lau, A.F., "Transfection of Mammalian Cells with PEG-Purified Plasmid DNA," <i>BioTechniques</i> 14:548, 550, Eaton Publishing Company (1993)

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	AR	<u>4</u>	Gorman, C., <i>et al.</i> , "High Efficiency DNA-Mediated Transformation of Primate Cells," <i>Science</i> 221:551-553, American Association for the Advancement of Science (1983)
	AS	<u>4</u>	Gorman, C., <i>et al.</i> , "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," <i>Proc. Natl. Acad. Sci. USA</i> 79:6777-6781, National Academy of Sciences (1982)
	AT	<u>4</u>	Harding, J.D., <i>et al.</i> , "Rapid isolation of DNA from complex biological samples using a novel capture reagent-methidium-spermine-sepharose," <i>Nucleic Acids Res.</i> 17:6947-6958 (1989)

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	AR	<u>5</u>	Hillen, W., <i>et al.</i> , "Preparation of Milligram Amounts of 21 Deoxyribonucleic Acid Restriction Fragments," <i>Biochemistry</i> 20:3748-3756, American Chemical Society (1981)
	AS	<u>5</u>	Hines, R.N., <i>et al.</i> , "Large-Scale Purification of Plasmid DNA by Anion-Exchange High-Performance Liquid Chromatography," <i>BioTechniques</i> 12:430-434, Eaton Publishing Company (1992)
	AT	<u>5</u>	Horn, N.A., <i>et al.</i> , "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Hum. Gene Ther.</i> 6:565-573, M.A. Liebert (1995)

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	AR	<u>6</u>	Johnson, T.R., <i>et al.</i> , "Large-Scale Isolation of Plasmid DNA and Purification of λ Phage DNA Using Hydroxylapatite Chromatography," <i>Analytical Biochemistry</i> 132:20-25, Academic Press (1983)
	AS	<u>6</u>	Just, L., <i>et al.</i> , "Rapid High-Yield Purification of Plasmids by Alkaline Extraction, PEG Precipitation and Agarose Gel Chromatography," <i>BioTechniques</i> 1:136-140, Eaton Publishing Company (1983)
	AT	<u>6</u>	Kasai, K., "Size-dependent chromatographic separation of nucleic acids," <i>J. Chromatogr.</i> 618:203-221, Elsevier Science Publishers, B.V. (1993)

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	AR	7	Kozak, M., "An analysis of 5'-noncoding sequences from 699 vertebrate messenger RNAs," <i>Nucleic Acid Res.</i> 15:8125-8148, Oxford University Press (1987)
	AS	7	Lech, K., and Brent, R., "Minipreps of Plasmid DNA," in <i>Current Protocols in Molecular Biology</i> , Greene Publishing Assoc. & Wiley, New York, NY, pp. 1.6.1-1.6.6 (1987)
	AT	7	Lew, D., <i>et al.</i> , "Cancer Gene Therapy Using Plasmid DNA: Pharmacokinetic Study of DNA Following Injection in Mice," <i>Hum. Gene Ther.</i> 6:553-564, M.A. Liebert (May 1995)

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	AR	<u>8</u>	Lis, J.T., "Fractionation of DNA Fragments by Polyethylene Glycol Induced Precipitation," <i>Methods Enzymol</i> , 65:347-353, Academic Press (1980)
	AS	<u>8</u>	Lis, J.T., and Scheif, R., "Size fractionation of double-stranded DNA by precipitation with polyethylene glycol," <i>Nucleic Acids Res.</i> 2:383-389, Oxford University Press (1975)
	AT	<u>8</u>	Mahon, K.A., <i>et al.</i> , "Prenatal lethality in a transgenic mouse line is the result of a chromosomal translocation," <i>Proc. Natl. Acad. Sci USA</i> 85:1165-1168, National Academy of Sciences (1988)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Marko, M.A., <i>et al.</i> , "A Procedure for the Large-Scale Isolation of Highly Purified Plasmid DNA Using Alkaline Extraction and Binding to Glass Powder," <i>Analytical Biochemistry</i> 121:382-387, Academic Press (1982)
	AS	2	McClung, J.K., and Gonzales, R.A., "Purification of Plasmid DNA by Fast Protein Liquid Chromatography on Superose 6 Preparative Grade," <i>Analytical Biochemistry</i> 177:378-382, Academic Press (1989)
	AT	2	Moore, D., "CsCl/Ethidium Bromide Preparations of Plasmid DNA," in <i>Current Protocols in Molecular Biology</i> , Greene Publishing Assoc. & Wiley, New York, NY, pp. 1.7.1-1.7.7 (1987)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	Mori, A., and Ogita, Z.-I., "Raid and Economical Method for Purification of Plasmid DNA," <i>The Physico-Chemical Biology</i> 29:41-45, Japanese Electrophoresis Society (1985)
	AS	<u>10</u>	Nabel, G.J., <i>et al.</i> , "Direct gene transfer with DNA-liposome complexes in melanoma: Expression, biological activity, and lack of toxicity in humans" <i>Proc. Natl. Acad. Sci. USA</i> 90:11307-11311, National Academy of Sciences (1993)
	AT	<u>10</u>	Nicoletti, V.G., and Condorelli, D.F., "Optimized PEG Method for Rapid Plasmid DNA Purification: High Yield from "Midi-Prep"," <i>BioTechniques</i> 14:532, 534, 536, Eaton Publishing Company (1993)

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	AR	<u>11</u>	Overbeek, P.A., <i>et al.</i> , "Tissue-Specific Expression in Transgenic Mice of a Fused Gene Containing RSV Terminal Sequences," <i>Science</i> 231:1574-1577, American Association for the Advancement of Science (1986)
	AS	<u>11</u>	Raymond, G.J., <i>et al.</i> , "Large-Scale Isolation of Covalently Closed Circular DNA Using Gel Filtration Chromatography," <i>Analytical Biochemistry</i> 173:125-133, Academic Press (1988)
	AT	<u>11</u>	Sambrook, J., <i>et al.</i> , "Extraction and Purification of Plasmid DNA," <i>Molecular Cloning, A Laboratory Manual, Second Edition</i> , Cold Spring Harbor Laboratory Press, pp.1.21-1.52 (1989)

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	AR	<u>12</u>	Summerton, J., <i>et al.</i> , "A Rapid Method for Preparation of Bacterial Plasmids," <i>Analytical Biochemistry</i> 133:79-84, Academic Press (1983)
	AS	<u>12</u>	Swanstrom, R., <i>et al.</i> , "Nucleotide sequence of cloned unintegrated avian sarcoma virus DNA: Viral DNA contains direct and inverted repeats similar to those in transposable elements," <i>Proc. Natl. Acad. Sci. USA</i> 78:124-128, National Academy of Sciences (1981)
	AT	<u>12</u>	Thompson, J., "A Review of High-Performance Liquid Chromatography in Nucleic Acids Research. III. Isolation, Purification, and Analysis of Supercoiled Plasmid DNA," <i>BioChromatography</i> 1:68-80 (1986)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>13</u>	Thompson, J.A., <i>et al.</i> , "Purification of Nucleic Acids by RPC-5 ANALOG Chromatography: Peristaltic and Gravity-Flow Applications," <i>Methods in Enzymology</i> 100:368-399, Academic Press (1983)
	AS	<u>13</u>	Westphal, H., <i>et al.</i> , "Promoter Sequences of Murine α A Crystallin, Murine α 2(I) Collagen or of Avian Sarcoma Virus Genes Linked to the Bacterial Chloramphenicol Acetyl Transferase Gene Direct Tissue-specific Patterns of Chloramphenicol Acetyl Transferase Expression in Transgenic Mice," <i>Cold Spring Harbor Symp. Quant. Biol.</i> 50:411-416, Cold Spring Harbor Laboratory Press (1985)
	AT	<u>13</u>	Willis, E.H., <i>et al.</i> , "Prep-A-Gene™: A Superior Matrix for the Purification of DNA and DNA Fragments," <i>BioTechniques</i> 9:92-99, Eaton Publishing Company (1990)

EXAMINER

DATE CONSIDERED

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FORM PTO-1449

**FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
1530.0550001/EKS/LAV

APPLICATION NO.
10/719,978

APPLICANT(S)
Budahazi *et al.*

FILING DATE
November 24, 2003

ART UNIT
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>14</u>	Yamada, O., <i>et al.</i> , "A new method for extracting DNA or RNA for polymerase chain reaction," <i>J. Virol. Methods</i> 27:203-210, Elsevier/North-Holland Biomedical Press (1990)
	AS	<u>14</u>	International Search Report for International Application No. PCT/US03/37665, European Patent Office, Netherlands, mailed on December 17, 2004
	AT	<u>14</u>	Dialog File 351, Accession No. 10142972, Derwent English language abstract for DE 43 21 904 (Document AM3)

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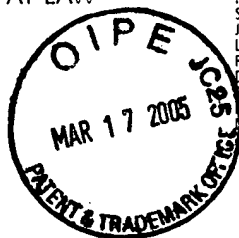
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	15	Dialog File 351, Accession No. 10382456, Derwent English language abstract for JP 09-509313 (Document AN3)
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*Practice Limited to Federal Agencies

March 17, 2005

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/719,978; Filed: November 24, 2003
For: **Process for Purification of Plasmid DNA**
Inventors: Budahazi *et al.*
Our Ref: 1530.0550001/EKS/LAV

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(b);
2. Form PTO-1449 (15 sheets) listing 56 cited documents (AA2-AD2, AN2-AP2, AS1, AT1, AL3-AP3, AR2-AT2, AL4, AM4, AR3-AT3, AR4-AT4, AR5-AT5, AR6-AT6, AR7-AT7, AR8-AT8, AR9-AT9, AR10-AT10, AR11-AT11, AR12-AT12, AR13-AT13, AR14-AT14, and AR15);
3. A copy of 52 cited documents (AN2-AP2, AS1, AT1, AL3-AP3, AR2-AT2, AL4, AM4, AR3-AT3, AR4-AT4, AR5-AT5, AR6-AT6, AR7-AT7, AR8-AT8, AR9-AT9, AR10-AT10, AR11-AT11, AR12-AT12, AR13-AT13, AR14-AT14, and AR15); and
4. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
March 17, 2005
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Andrea Do Kamage #43,703
for

Eric K. Steffe
Attorney for Applicants
Registration No. 36,688

EKS/LAV:kim
Enclosures

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